

## REMARKS

The status of the application is as follows: claims 1-9 and 25-37 are pending. Claims 10-24 were withdrawn from consideration pursuant to an earlier election. Claims 1, 5, 6, 7, 27, 28, 30, 31, 35, 36 and 37 are amended. New claim 38 is added. Entry and consideration of the amendments are earnestly requested.

Basis for the amendments and the new claim can be found at page 6, lines 19-23, page 7, lines 17-29, pages 8 and 9 in their entirety, page 10, lines 23-28 and in Figures 1 and 2.

Applicants acknowledge with appreciation the Examiner's withdrawal of the rejections set forth in the prior Office Action.

### Supplemental Amendment

The Examiner based the Action on the claims as submitted in the Supplemental Amendment faxed to the Examiner on May 25, 2006. Applicant had considered the faxed submission a formal amendment, not an informal one as the Examiner stated in the Action. For clarity of the record, applicant submits on even date herewith the Supplemental Amendment submitted on May 25, 2006.

### Objection to the Specification

In view of the remarks expressed below and the amendment to the claims, applicant submits that the definitions of and use of the phrases "half life of binding" and "half-life of release" set forth in the specification of the Subject Application are not relevant to an understanding of the claimed subject matter by those skilled. Withdrawal of the objection is requested.

### Claim Rejections

#### 35 U.S.C. §112, first paragraph

The Examiner rejected claims 1-9 and 30-34 under 35 U.S.C. §112, first paragraph because the specification does not enable one skilled in the art to make a capture device having a

specific “half life of release”. The Examiner relies on Lodish *et al.*, MOLECULAR CELL BIOLOGY, Section 2.3 (2000) and Heller *et al.*, 22 J.App. Polym. Sci. 1991 (1978) for his position that the initial concentration of biomolecules in the devices environment, the solubility of the biomolecules in water, the surface area of the device, and the pH and buffer capacity of the devices environment must be defined to enable one skilled in the art to make and use the claimed capture device.

Although Applicant continues to disagree with the Examiner, in the interest of advancing the prosecution of the Subject Application, applicant has amended claims 1, 30 and 31 to remove the “half life of release” language and to describe the biomolecule capture device in terms of the orientation of the maleic anhydride relative to the substrate to position the anhydride for binding to biomolecules when the device is in use. Withdrawal of the rejection under 35 U.S.C. §112, first paragraph is requested.

35 U.S.C. §112, second paragraph

The Examiner rejected claims 1-9 and 25-37 under 35 U.S.C. §112, second paragraph, as being indefinite due to the “half life of release” language in claims 1-9 and 30-34. Claims 25-29 and 35-37 do not include that phrase, so it is assumed that the Examiner intended to reject only claims 1-9 and 30-34 under this section. Based on the amendments to independent claims 1, 30 and 31 to remove “half life of release,” withdrawal of the rejection under 35 U.S.C. §112, second paragraph is requested.

35 U.S.C. §102(b)

The Examiner rejected claims 1-3, 5-9, 25 and 27-37 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 3,679,653 to Schuck & Wildi (the ‘653 Patent). The Examiner cited specifically col. 6, lines 19-28. Applicant respectfully disagrees with the Examiner’s interpretation of the teachings of the ‘653 Patent.

The ‘653 Patent describes products wherein a hormone is covalently bound to a selected polymer and a process for their production. At column 2, lines 56-60, and again at col. 5, lines 12-22, the ‘653 Patent states that the products of the invention are hormonally-active polymer-

hormone products wherein the hormone is bound covalently to a polymer through a group on the hormone which is not essential for its hormone activity. A preferred polymer is described as having chains of repeating carboxylic acid or carboxylic acid anhydride units, or units of carboxylic acid or carboxylic acid anhydride groups separated by carbon chains of not more than four carbon atoms. The polymer is formed by polymerization of polymerizable acids or anhydrides or by copolymerizing a polymerizable acid or anhydride with another copolymerizable monomer. At col. 6, lines 15-28, the '653 Patent states that a preferred polymeric material is the polymer of an olefinically unsaturated polycarboxylic acid or derivative with itself or in approximately equimolar portions with at least one other monomer copolymerizable therewith. The carboxylic acid derivative can be maleic acid,  $\alpha$ ,  $\alpha$ -dimethyl maleic acid and anhydrides of those acids. The '653 Patent thus teaches the use of maleic anhydride to make the polymeric substrate to which the hormone is then covalently bound. In the polymerization process, it is believed that the maleic anhydride units change to succinic acid units. See for example, the structure for the polymer in col. 5 at line 30. In that structure, there is no double bond between  $CR_A$  and  $CR_B$  even if  $q$  is zero because  $R_A$  and  $R_B$  are either hydrogen or something more complex and  $n$  is at least 8 (*see* col. 6, line 4; *compare* the Subject Application at page 9, lines 1-2). In maleic anhydride, one of  $X$  and  $Y$  of the structure shown in col. 5 would be eliminated and the other would be joined as a single oxygen bound to the carbonyls and  $n$  would have to be zero. The resulting polymer of the '653 Patent is not a maleic anhydride compound bound to a substrate. The maleic anhydride used in the '653 Patent becomes the substrate and changes form in the process. In addition, there is no teaching that the hormone reversibly attaches to a maleic anhydride.

In the claimed capture device, the maleic anhydride compound is not copolymerized with the substrate. It is covalently bound to a surface of the substrate. As stated in claims 1 and 30, for example, the maleic anhydride compound is bound through a functional group on one of the molecular 2 or 3 position of the maleic anhydride to the surface of the substrate. As stated in claim 35, the maleic anhydride is bound to the surface of the substrate at one of the disubstituted positions. The orientation of the maleic anhydride places it in a position one the substrate to expose the carbonyls of the anhydride portion for reversible binding with, or reversible capture of, a biomolecule. Referring to Figures 1 and 2 of the Subject Application, it can be seen that the

maleic anhydride is not copolymerized with the substrate, depicted in that figure by the solid black circle.

Applicant submits that the '653 Patent does not disclose each of the elements of the claimed biomolecule capture device of the Subject Application. Withdrawal of the rejection of claims 1-3, 5-9, 25 and 27-37 under 35 U.S.C. §102(b) is requested.

#### 35 U.S.C. §103(a)

The Examiner rejected claims 4 and 26 under 35 U.S.C. §103(a) as being unpatentable over the '653 Patent in view of the Abstract of Schmincke-Ott & Bisswanger, 10 Prep. Biochem. 69 (1980). The Schmincke-Ott & Bisswanger Abstract describes a method of adsorbing proteins using aminohexylagarose. It has nothing to do with a device comprised of a substrate having a maleic anhydride bound to the substrate in an orientation that allows reversible capture of biomolecules. As described above, the '653 Patent describes a polymeric substrate using maleic anhydride as one of the starting materials in the polymerization reaction. If aminohexylagarose were to be used as one of the monomers to make the polymer of the '653 Patent, the resulting polymer would still not produce the claimed biomolecule capture device.

Applicant submits that the combination of the '653 Patent and the Schmincke-Ott & Bisswanger Abstract do not teach or suggest the subject matter of applicant's claimed biomolecule capture device and would not render the claimed device obvious to those of ordinary skill in the relevant art. Withdrawal of the rejection of claims 4 and 26 under 35 U.S.C. §103(a) is requested.

#### Other Amendments

Nonlimiting amendments have been made to claims 5, 6 and 27 to add derivatives of the alkyl groups listed. Basis for the addition can be found in the Specification at pages 8 and 9.


Nonlimiting amendments have been made to claims 7, 28, 34, 35, 36 and 37 to add clarity to the claims. Basis for the amendments can be found at pages 7, 8 and 9 of the Specification

and in Figures 1 and 2. New claim 38 has been added to claim the embodiment disclosed at page 6, lines 21-23. No new matter is introduced by the amendments.

Conclusion

Entry and consideration of the amendments and reconsideration and allowance of all pending claims in light of the foregoing are earnestly solicited. If the undersigned can be of assistance in advancing the Subject Application to allowance, the Examiner may contact the undersigned at the number set forth below.

Respectfully submitted,

  
Christine R. Ethridge  
Reg. No. 30,557

KIRKPATRICK & LOCKHART NICHOLSON GRAHAM LLP  
Henry W. Oliver Building  
535 Smithfield Street  
Pittsburgh, PA 15222-2312  
Phone: (412) 355-8619  
Fax: (412) 355-6501